

The Clinical Information

S-Shearwave™ Elastography Liver Evaluation: Recommended Values

RS80A with Prestige

Samsung Medison Clinical Research Group

Assessment of liver disease

Liver fibrosis, which may lead to cirrhosis, is a sign of chronic liver disease. Liver stiffness is usually indicative of fibrosis or steatosis, which are suggestive of numerous disease conditions including cirrhosis, hepatitis, and Non-Alcoholic Fatty Liver Disease (NAFLD). Accurate diagnosis and staging of liver fibrosis is essential for the prognosis and management of chronic liver diseases. Liver biopsy has traditionally been considered the gold standard for evaluating liver fibrosis, however, it has inherent limitations (invasiveness, sampling error, inter-/intraobserver variability).^{3,8,9} Liver elastography is an innovative technique to assess tissue stiffness and hence fibrosis.

Conventional B-mode ultrasound only provides anatomical information. By adding shearwave elastography to the exam, stiffness values in patients with liver fibrosis can now evaluated. Shearwave elastography aids in distinguishing between a simple fatty liver versus liver fibrosis. There are studies assessing the use of shearwave elastography to repeatedly measure liver stiffness (longitudinal surveillance).¹⁰ Shearwave elastography can also distinguish if a suspected hemangioma found in B-mode imaging is stiff or soft and aid in the prediction of the long-term prognosis of disease (i.e. chronic liver disease).

Liver stiffness evaluation with S-Shearwave elastography

Samsung's S-Shearwave™ is a technology that detects the velocity of the shearwave propagated through a targeted area in liver tissue, then displays the numerical measurement of stiffness in kPa or m/s. The "shearwave" is a perpendicular wave produced as a result of multiple, focused, high-intensity, short-duration acoustic pulses generated lateral to the area of interest (Fig. 1). The shearwaves are tracked as they travel through this region of interest. The shearwave propagation speed is used to calculate the stiffness of the tissue. S-Shearwave displays the numerical measurement of elasticity (stiffness) as either shearwave velocity (m/s) or as Young's Modulus in kPa. Shearwaves travel faster in stiffer tissues. In the liver, the loss of elasticity corresponds closely to the amount of hepatocellular damage (fibrosis).



Fig1. Graphic depiction of an ultrasound pulse (blue arrow) and resultant shear waves (red perpendicular waves) used during S-Shearwave elastography. The shearwaves propagate through the region of interest (green box) to determine the stiffness of the liver tissue/lesion.

EXPERIENCE A New Healthcare Solution

Methodology

S-Shearwave on Samsung's RS80A with Prestige is conducted on the liver by first using B-Mode imaging to locate the area of interest. The Region of Interest (ROI) box is then placed in an area of the right lobe of liver and several S-Shearwave measurements are taken (Fig. 2). The measurements are conducted while the patient suspends respiration. The ROI box should not be placed in or immediately lateral to any vasculature. The velocity of the shearwaves are used to calculate the stiffness (kPa) of the targeted area within the ROI.



patient's liver. After each sample, S-Shearwave indicates the stiffness measured in kPa, the depth of the region of interest, and the RMI (Reliable Measurement Index).

The average of the measurements is used to estimate the degree of liver stiffness (Fig. 3). Additionally, the Reliability Measurement Index (RMI) and Variation Range (VR) are provided in the S-Shearwave Profile. The RMI (reliability of the measurement) is a quality control parameter that is calculated by the weighted sum of two factors: the residual of the wave equation, and the magnitude of the shearwave. Therefore, high RMI values are strongly correlated with reproducible measurements. An RMI of 0.0 would indicate significant error, whereas an RMI of 1.0 would indicate no error). While in the S-Shearwave Profile display, the user can easily deselect any unreliable measurements depending on its RMI.

EXPERIENCE A New Healthcare Solution

This could possibly improve the performance of shearwave elastography and could be used as a criterion to assess the quality of the data. The VR bar visually displays the difference between the smallest and the largest data item in the measurement set. The VR intuitively shows the uniformity of tissue stiffness within the selected ROI. A wider range indicates there is less tissue stiffness uniformity. A narrow VR bar indicates there is more tissue stiffness uniformity in the measurement set of data. Ultimately, S-Shearwave may help reduce the number of conventional liver biopsies by providing quantitative tissue characteristic information that can be used to estimate the degree of fibrosis.



Fig 3. The S-Shearwave Profile graphs the measurements including kPa, RMI, percentiles, and median values. Additionally, an interquartile range (IQR) of all successful measurements of median value is calculated.

Guidelines for Liver Shear Wave Elastography

There are many studies looking at the role of elastography in different conditions and there are a number of specific findings for each condition, which include specific cut-off points indicating fibrosis. These vary slightly depending on the study and disease and therefore the absolute levels will have different clinical significance in different clinical settings.³ Table 1 gives the recommended values for shearwave elastography in the evaluation of the liver from a 300-patient study conducted at Garran Medical Imaging, Australia.

Condition	Normal	Dysfunction (F1)	Fibrosis present (F2 or F3)	Cirrhosis F4*	Odds ratio
No known disease	<5.7	<8	<8	>14	
Hepatitis C***	<5.7	<7.6	>7.6	>11.6	~46
Hepatitis B***	<5.7	<7.0	>7.0	>11.2	~34
NAFLD**	<5.7	<8	>8	>17	

Table 1: Shear Wave Elastography Liver Evaluation Recommended Values 2016

Notes: *recommend hepatology consult / **Yoneda et al: Gut. 2007 Sep; 56(9): 1330-1331.

*** Modified from Tsochatzis et al: J Hepatol 2011;54:650-659. / Overall reference jeong et al: Ultrasonography 2014;22:149-160.

Table 1. Results of Dr. Iain Duncan's 300-patient study using Samsung's RS80A with Prestige's S-Shearwave elastography to evaluate the liver. Note: Refer to Table 2 for the METAVIR scoring system (F1, F2, F3, F4).

METAVIR Scoring System				
A - Histological Activity	A - Histological Activity			
A0 - No Activity	F0 - No Fibrosis			
A1 - Mild Activity	F1 - Portal Fibrosis Without Septa			
A2 - Moderate Activity	F2 - Portal Fibrosis With Rare Septa			
A3 - Severe Activity	F3 - Numerous Septa Without Cirrhosis			
N/A	F4 - Cirrhosis			

Table 2: METAVIR Scoring System¹¹

Table 2. The METAVIR scoring system provides a model for interpreting a liver biopsy. The METAVIR score is composed of two categories ('A' = histological activity and 'F' = fibrosis) with a numbered grading system to indicate the amount of inflammation (activity) and the amount of fibrosis (Table 1). Using the METAVIR scoring system, liver fibrosis is evaluated semi-quantitatively and staged using a point scale ranging from 0-4.¹¹

Clinical applications:

Assessing the degree of liver fibrosis is an important factor when determining the appropriate course of treatment for liver disease to include NAFLD, Hepatitis B, and Hepatitis C.

Nonalcoholic fatty liver disease refers to a range of liver conditions affecting people who drink little to no alcohol. Too much fat stored in the liver cells is a characteristic of NAFLD. NAFLD is one of the most common causes of chronic liver injury in many countries around the world.⁴ Nonalcoholic steatohepatitis (NASH) occurs when the fatty infiltration occurs along with liver inflammation. A relevant proportion of NAFLD patients, particularly those with non-alcoholic steatohepatitis (NASH), may progress to cirrhosis and its complications.¹²

Hepatitis B and Hepatitis C are primarily transmitted by contact with infected blood although Hepatitis B may also be transmitted through infectious semen or other bodily fluids. Routes of transmission may include sharing contaminated needles, needlestick, birth to an infected mother, or sexual contact with an infected person.⁶ The risk for chronic infection with Hepatis B varies according to the age at. Approximately 90% of infants and 25%–50% of children aged 1–5 years will remain chronically infected with the Hepatitis B virus. By contrast, approximately 95% of adults recover completely from infection and do not become chronically infected.⁵ Alternatively, approximately 75%–85% of people infected with Hepatitis C develop chronic infection. Of those with chronic Hepatitis C, 60%–70% will develop chronic liver disease, 5%–20% will develop cirrhosis, and 1%–5% will die from cirrhosis or liver cancer.⁵

The clinical applications of shearwave elastography are widespread and growing as this technique is currently the only reliable quantitative and non-invasive method of assessing hepatocellular damage. Currently it is being used in:¹³

EXPERIENCE A New Healthcare Solution

- 1. Chronic viral hepatitis (hepatitis B and C) for diagnosis of fibrosis and cirrhosis
- 2. Other chronic hepatitis
- 3. Fatty liver with hepatitis (NASH and NAFLD)
- 4. Monitoring for drug toxicity (e.g. methotrexate)
- 5. Alcoholic liver diseases
- 6. Liver transplantation
- 7. Portal hypertension

Other possibilities include progress assessments in intervention related to fatty liver disease and other causes of liver dysfunction.¹³ Shear Wave Elastography elastography can be used to assess and monitor the gradual progression of liver fibrosis without the having to rely on invasive liver biopsy procedures.

Supported Systems	References			
- RS80A with Prestige	 Yoneda M, Fujita K, Inamori M, et al. Transient elastography in patients with non-alcoholic fatt liver disease (NAFLD). Gut. 2007 Sep; 56(9): 1330-1331. 			
	 Tsochatzis EA, Gurusamy KS, Ntaoula S, et al. Elastography for the diagnosis of severity of fibrosis in chronic liver disease: a meta-analysis of diagnostic accuracy. J Hepatol. 2011 Ap 54(4): 650-659. 			
	 Jeong WK, Lim HK, Lee HK, et al. Principles and clinical application of ultrasound elastograph for diffuse liver disease. Ultrasonography 2014; 33(3): 149-160. 			
	4. Angulo P. Nonalcoholic fatty liver disease. N Engl J Med 2002181221–1231.			
	 Hepatitis C FAQs for the public. (2016, May 23). Retrieved from http://www.cdc.gov/hepatitis/c cfaq.htm. 			
	 The ABCs of hepatitis. (2016). Retrieved from http://www.cdc.gov/hepatitis/resources professionals/pdfs/abctable.pdf. 			
	 Schiavon LL, Narciso-Schiavon JL, Carvalho-Fiho RJ. Non-invasive diagnosis of liver fibrosis i chronic hepatitis C. World J Gastroenterol. 2014 Mar 21; 20(11): 2854-2866. 			
	 Papastergiou V, Tsochatzis E, Burroughs AK. Non-invasive assessment of liver fibrosis. Ann Gastroenterol. 2012; 25(3): 218-231. 			
	 Bedossa P, Dargère D, Paradis V. Sampling variability of liver fibrosis in chronic hepatitis (Hepatology. 2003; 38: 1449–57. 			
	 Martinez SM, Foucher J, Combis JM, et al. Longitudinal Liver Stiffness Assessment in Patient with Chronic Hepatitis C Undergoing Antiviral Therapy. PLOS. 2012 Oct; 7(10): 1-7. 			
	11. Bedossa P, Poynard T. An algorithm for the grading of activity in chronic hepatitis C. The METAVIR Cooperative Study Group. Hepatology. 1996;24(2):289-93.			
	 Petta S, Craxì A. Hepatocellular carcinoma and non-alcoholic fatty liver disease: from a clinica to a molecular association. Curr Pharm Des 2010; 16: 741–52. 			
	13. Garran Medical Imaging. Liver Elastography: What is liver elastography. https://garranmedicalimaging.com.au/elastography-of-the-liver/. Accessed April 25, 2017.			



© 2017 Samsung Medison All Rights Reserved.

Samsung Medison Reserves the right to modify any design, packaging, specifications and features shown herein, without prior notice or obligation.